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How Quality of Life as Patient-Reported Outcome Has Been Studied for Rheumatoid Arthritis in Chinese-Speaking Population

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ABSTRACT

Objective: To review the use of health-related quality-of-life (HRQOL) instruments as patient-reported outcome in patients with rheumatoid arthritis (RA) in studies that have been published in Chinese-speaking populations. **Methods:** Overlapping searching strategy was used using four publication databases: PubMed and EMBASE for English publications and Wanfang and CNKI for Chinese publications. Entries published between January 1, 1990, and July 31, 2014, were retrieved and then reviewed independently by two researchers. The identified studies were summarized according to information source, publishing year, study location, and study type. The validation studies were examined closely in terms of their sample sizes and psychometric properties. **Results:** There were 99 studies from the databases selected for review. Among the studies reviewed, most studies were conducted in Mainland China. There was a clear overall increasing trend in the number of studies in recent years. Generic instruments were more frequently used by researchers outside China. Another observation was that most instruments were used without previous validation either in any Chinese-speaking population with RA or in the specific country that it was used. **Conclusions:** The importance of patient-reported quality of life as an outcome indicator in patients with RA is more and more realized in Chinese-speaking regions during the past two decades. To facilitate the use of HRQOL for better management of patients, and improve the quality of research, there is a strong need of validating the HRQOL instruments in more locations with a larger population, more comprehensive validity, and potential cross-cultural validation in future.

Keywords: Chinese, patient-reported outcome, quality of life, rheumatoid arthritis.

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Introduction

Rheumatoid arthritis (RA) is a chronic systemic inflammatory disorder characterized by inflammation in the synovium of joints, malaise, morning stiffness, and fatigue. It is associated with progressive joint destruction and, depending on the severity, may be accompanied by systemic manifestations including lung disease, rheumatoid nodules, and effects on the cardiovascular system. Patients with RA tend to undergo exacerbations and periods of remission. If left untreated, over the course of 10 to 20 years RA may lead to significant disabilities and a severe reduction in the patient's quality of life. The prevalence of RA, at 0.5% to 1% [1], is relatively constant in many populations, but factors such as sex, race, and smoking status can cause a variation in this level [2,3]. In China, RA is among the 10 main chronic diseases, with increasing morbidity: from 8.6% in 2003 to 10.2% in 2008 [4]. According to the Second National Survey of Disabled Population in China in 2006, arthritis is the second most common cause of disability [5]. Although the data would include both osteoarthritis and RA, RA would be expected to contribute significantly to this burden because of the higher proportion of older women (in whom RA is more commonly encountered) and the substantially higher drug treatment cost for RA. Considering that the total size of the Chinese population with disabilities is more than 80 million, the burden from RA could be enormous.

In recent years, the importance of measuring health-related quality of life (HRQOL) has been increasingly recognized by clinicians and policymakers to inform patient management and policy decisions, especially in the management of patients with chronic diseases [6]. For clinicians, by gathering needed data about patients' functioning and well-being not captured by other clinical markers through HRQOL measurements, they could be alerted to potential problems that require intervention. For decision makers or policymakers, HRQOL measurements could be the evidence when evaluating alternative treatments [7]. Generally speaking, HRQOL measures could be either patient reported or clinician reported. As part of patient-reported outcomes [8], measuring patient-reported HRQOL is especially important for diseases, conditions, or treatment effects that are known only to the patient but are of clinical relevance to the

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management of the disease or condition, for example, intensity of pain. In this research, we focused on patient-reported HRQOL.

RA being a deteriorative chronic disease, as described above, it is important to keep tracking over time the HRQOL reported by patients with RA to assess disease progression as well as effectiveness of treatment. In Western countries, besides the generic HRQOL instruments, for example, short-form 36 health survey (SF-36) [9] and its shorter versions, and the EuroQol five-dimensional questionnaire [10], many RA-specific HRQOL instruments such as the health assessment questionnaire (HAQ) [11], the rheumatoid arthritis quality of life [12], and Arthritis Impact Measurement Scales 2 (AIMS2) [13] have been created, validated, and then widely used in clinical settings. In addition, the importance of measuring the HRQOL is attested by the fact that the HAQ score was listed as a component of the American College of Rheumatology criteria [14] for diagnosing RA. There is no clear picture, however, how HRQOL has been studied among Chinese-speaking patients with RA, especially in Mainland China. Considering the sheer size of RA sufferers in China alone, a clearer understanding of the current status of HRQOL tools available for use among Chinese-speaking patients with RA would contribute toward better management of these patients. Better management of these patients is likely to produce significant health as well as economic benefits.

In our present study, we aimed to review the development, validation, and use of HRQOL instruments that have been published globally in English and locally in Chinese as an outcome measure in Chinese-speaking patients with RA, to address three research questions:

1. Which HRQOL instruments have been created and validated for Chinese-speaking patients with RA?
2. Which HRQOL instruments have been used to measure the HRQOL of Chinese-speaking patients with RA?
3. Have the HRQOL instruments been used appropriately after sufficient validation?

Methods

Data Source

Electronic databases of PubMed and EMBASE, and Wanfang and CNKI, which are the two leading Chinese publication databases, were searched for English and Chinese publications, respectively. The overlapping strategy of searching several electronic databases was used to identify potentially relevant articles [15].

Time Frame

A time frame was set and all entries published between January 1, 1990, and July 31, 2014, were retrieved and analyzed. The final search of the databases concluded at August 1, 2014.

Searching Strategy

Studies were retrieved using a key word filtration process. The key words "(Rheumatoid Arthritis) AND (Quality of life) AND (China OR Chinese)" were used to seek matches in the English publication databases PubMed and EMBASE, while the corresponding Chinese translations of "(Rheumatoid Arthritis) AND (Quality of life)" were used to seek matches in the Chinese publication databases Wanfang and CNKI. Considering the nature of the Chinese publication databases, the translation of the key word "(China OR Chinese)" was deemed unnecessary and hence omitted and not used in the search.

Culling Criteria

After two researchers had independently read the titles, abstracts, and full texts, if necessary, publications that had at least one HRQOL instrument validated or used were included. Even though no HRQOL instrument was mentioned, studies with the American College of Rheumatology response rate were still included because health assessment questionnaire – disability index is part of the American College of Rheumatology response criteria. In the culling process, because our objective was to retrieve original prospective studies, reviews and retrospective studies were excluded.

Qualitative Analysis

The identified RA studies were first classified according to the information source (publication in English/publication in Chinese). Then, within each classification, the retrieved studies were further organized into different categories, according to year of publication, location of study, and type of study (validation/application). Furthermore, the number of publications of each specific HRQOL instrument in the identified studies was

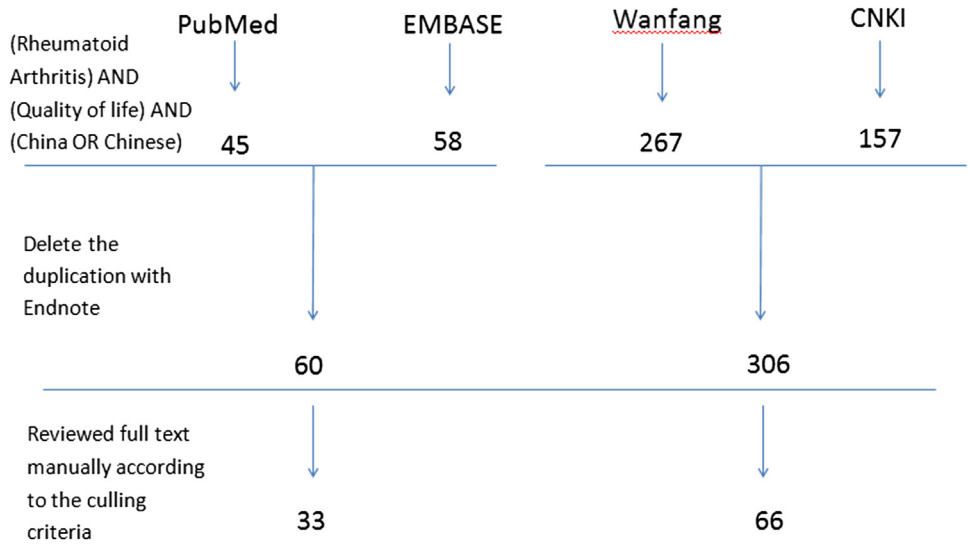

Fig. 1 – Flow chart of the selection process for articles.

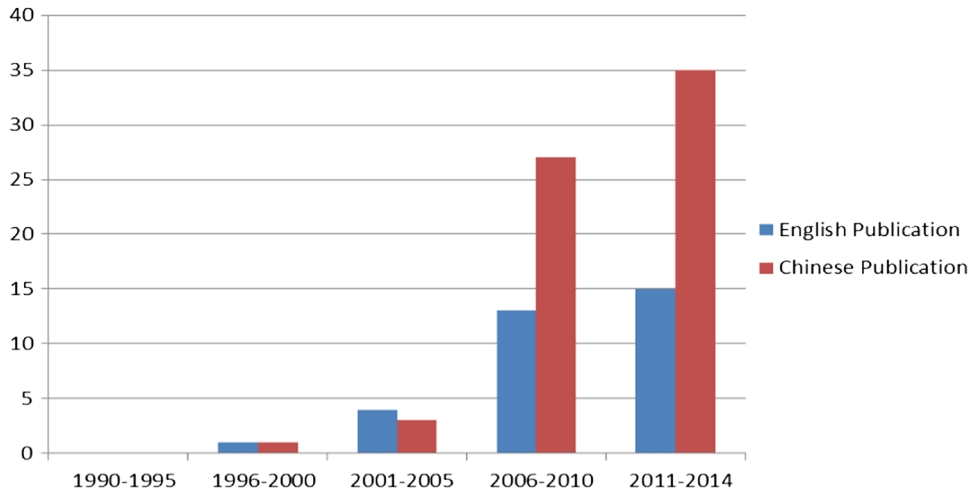

Fig. 2 – Time distribution of studies with HRQOL instruments on patients with RA. HRQOL, health-related quality of life; RA, rheumatoid arthritis.

summarized by location of study, in which the validation studies were identified. Considering the economic and social development status, the location of study was categorized into two classes: Mainland China and Other Chinese-speaking areas (Taiwan, Hong Kong, and Singapore). Finally, the validation studies were examined closely in terms of their sample sizes, and the psychometric properties, namely, internal consistency, test-retest reliability, content validity, construct validity, criterion validity, and responsiveness.

Results

There were 45 and 58 English publications retrieved from PubMed and EMBASE, respectively, and 267 and 157 Chinese publications from Wanfang and CNKI, respectively. After deleting duplications, in total, 60 publications in English and 306 publications in Chinese were retrieved from the electronic databases with the use of the overlapping search strategy. After the culling process, 99 studies from the publication databases (33 in English and 66 in Chinese) fulfilled the inclusion criteria and therefore were further reviewed and classified (Fig. 1).

To evaluate the chronological change in the number of studies on RA with HRQOL instruments, we grouped the studies in chronological categories, namely, from 1990 to 1995, 1996 to 2000, 2001 to 2005, 2006 to 2010, and 2011 to 2013 (Fig. 2). There is an overall trend consistent across the data sources: there was clearly a sharp increase after 2005, and within less than 4 years from 2011 to August 2014, the number of studies had overtaken that of the previous 5 years (2006–2010).

Among the studies published in English, the number of studies conducted in China (N = 17) and other Chinese-speaking countries/areas (N = 16), including Taiwan, Hong Kong, and Singapore, was comparable. It is not surprising, however, that all studies published in Chinese (N = 66) were conducted in Mainland China. In terms of type of studies, it is consistent in both English and Chinese publications that the number of studies using the HRQOL instruments was much more than the number of studies of validations on HRQOL instruments (Table 1).

A difference can be observed, however, in researchers' preference of using the HRQOL instruments between Mainland China and other Chinese-speaking areas. It could be seen from the summary as presented in Table 2 that generic instruments were more commonly used by researchers from other Chinese-speaking areas, whereas disease-specific instruments seemed to be preferred by researchers from Mainland China. To be more specific, there were several instruments that were most frequently used: the SF-36 and the HAQ in both Mainland China and other Chinese-speaking areas, and Zung self-rating anxiety scale/self-rating depression scale and the Rheumatoid Arthritis Quality of Life Questionnaire (RAQOLQ) in Mainland China only.

Among the retrieved validation studies, there were four instruments validated in Singapore—the EuroQol five-dimensional questionnaire [16], the SF-36 [17], AIMS2 [18], and the HAQ [19]—and three instruments, namely, the RAQOLQ [20], Arthritis Impact Measurement Scales 2 Short Form [21], and the Self Care Behavior Evaluation Questionnaire-Rheumatoid Arthritis [22], validated in Mainland China.

Discussion

In our present study, we attempted to review the extent of adoption and application of the Chinese version of HRQOL instruments in Chinese-speaking patients in the past two decades by examining published articles reporting such use. Although we did not retrieve any published article from 1990 to 1995, our results show a trend of gradual increase in the number of

Table 1 – Summary of studies reviewed.

Study attribute	English publication (N = 33)	Chinese publication (N = 66)
Number of publications by year		
1990–1995	0	0
1996–2000	1	1
2001–2005	4	3
2006–2010	13	27
2011–2014	15	35
Number of publications by country/area		
Mainland China	17	66
Other (Taiwan, Hong Kong, and Singapore)	16	0
Type of study		
Validation	4	3
Application	29	63

Table 2 – Summary of validation and use of HRQOL instruments.

QOL instrument	Mainland China	Other (Taiwan, Hong Kong, and Singapore)
Generic		
EQ-5D	1	1* + 1
SF-36	17	1* + 7
SF-12	4	1
SF-6D		1
HUI		1
WHOQOL-BREF	3	1
WPAI:GH		1
FACIT-F		4
GDS		1
HADS		1
Zung SAS/SDS	15	
SCL-90	1	
HAMA/HAMD	1	
Disease specific		
HAQ	24	1* + 4
RAQOLQ	1* + 21	
AIMS	1	
AIMS2	2	1*
AIMS2-F	1*	
SBCEQ-RA	1*	

AIMS, Arthritis Impact Measurement Scales; AIMS2, Arthritis Impact Measurement Scales 2; AIMS2-F, Arthritis Impact Measurement Scales 2-Short Form; EQ-5D, EuroQol five-dimensional questionnaire; FACIT-F, Functional Assessment of Chronic Illness Therapy-Fatigue; GDS, Geriatric Depression Scale; HADS, Hospital Anxiety and Depression Scale; HAMA/HAMD, Hamilton Anxiety/Hamilton Depression; HAQ, health assessment questionnaire; HRQOL, health-related quality of life; HUI, health utilities index; QOL, quality of life; RAQOLQ, Rheumatoid Arthritis Quality of Life Questionnaire; SAS/SDS, self-rating anxiety scale/self-rating depression scale; SBCEQ-RA; Self Care Behavior Evaluation Questionnaire-Rheumatoid Arthritis; SCL-90, Symptom Check List-90; SF-36, short-form 36 health survey; SF-12, short-form 12 health survey; SF-6D, six-dimensional health state short form (derived from SF-36); WHOQOL-BREF, World Health Organization Quality of Life - Abbreviation; WPAI:GH, Work Productivity and Activity Impairment: General Health.
* Validation study.

published articles between 1996 and 2000, followed by a much greater increase thereafter. This trend of increasing publication of HRQOL articles in patients with RA is actually in line with the gradual realization of the importance of incorporating HRQOL as an outcome measure internationally. This also indicates that the use of HRQOL instruments in patients with RA is gaining more attention and better acceptance by clinicians and researchers for use in Chinese-speaking populations, particularly in Mainland China.

Regarding the use of HRQOL instruments, different preferences of researchers from Mainland China and other Chinese-speaking areas were observed. This may be partially explained by the experience of use of the instruments by the researchers as well as the relevance of the instruments for the setting; for example, the RAQOLQ as an RA-specific instrument originally developed in Chinese was used widely in Mainland China only. Another possible explanation would be the availability of a validated instrument (whether generic or disease specific) when the study was performed. Actually this would explain another observation that there were much more publications about the application than the validation of the instruments, both in English and in Chinese. Before being applied in studies or clinical practice, it is mandatory that all HRQOL instruments should be validated in terms of psychometric properties [23]. As shown in the summary table (Table 1), however, application studies greatly outnumbered validation studies. This may imply that most of the instruments were used without previous validation in any Chinese-speaking populations with RA. Another plausible explanation may be that Chinese versions of some of these generic instruments may be validated in other Chinese-speaking patient groups and the general populations, but this is still less than ideal.

First, as suggested in previous studies [23], to provide initial estimates of reliability and validity, samples sizes should be at least 200 cases, if feasible. Among the seven validation studies conducted in either Singapore or China, the sample sizes were far less than recommended, except for the validation study of the SF-36 (Table 3). Second, although the reliability, including internal consistency and test-retest reliability, was well performed in these studies, the validations on validities and responsiveness were comparably less well undertaken.

Last, before cross-cultural application of an HRQOL instrument, there should be a cross-cultural validation and adaptation to ensure level of comprehensibility and cognitive equivalence of the translation on the same item across different cultures [24,25]. The EuroQol five-dimensional questionnaire, the SF-36, the HAQ,

Table 3 – Validation studies of HRQOL instruments in Chinese-speaking population with RA.

HRQOL instrument	Validation location	Sample size	Psychometric property validated					
			Internal consistency	Test-retest reliability	Content validity	Construct validity	Criterion validity	Responsiveness
EQ-5D	Singapore	22	X	X		X		
SF-36	Singapore	401	X	X		X	X	X
HAQ	Singapore	42	X	X	X		X	
AIMS2	Singapore	81	X	X	X	X	X	
AIMS2S-F	Shanghai	51	X	X		X		
RAQOLQ	Shanghai	50	X	X	X			
SBCEQ-RA	Shanghai	48	X	X	X			

AIMS2, Arthritis Impact Measurement Scales 2; AIMS2-F, Arthritis Impact Measurement Scales 2-Short Form; EQ-5D, EuroQol five-dimensional questionnaire; HAQ, health assessment questionnaire; HRQOL, health-related quality of life; RA, rheumatoid arthritis; RAQOLQ, Rheumatoid Arthritis Quality of Life Questionnaire; SBCEQ-RA, Self Care Behavior Evaluation Questionnaire-Rheumatoid Arthritis; SF-36, short-form 36 health survey.

and AIMS2 were used in all Chinese-speaking populations with RA but validated only in Singapore. Although there are no major differences in the use of Chinese language itself between Singapore and China, the economic development, culture, and living conditions in these two countries are notably different. Singapore is a multiracial country and among the most westernized among the Asian countries. Hence, the Chinese-speaking population in Singapore is likely to be influenced more by Western culture as well as cultures of other major ethnic groups in Singapore. Furthermore, being a developed economy with high incomes, the expectation and response of the Singaporean population may pose a subtle but important difference from populations in China and Chinese-speaking populations in regions of lesser economic development. All these could lead to a significant difference in patients' understanding, appreciation, and response to the HRQOL instrument. In fact, the same concerns also apply for the three validation studies conducted in Mainland China: the sample size of the studies was fairly small and data were collected only in Shanghai, the largest and most developed city in China. Considering the difference in economic development and culture between major cities and vast rural regions, and between south and north China, the data should be collected at more than one location to increase the representativeness.

Conclusions

The importance of research and studies on patient-reported HRQOL of patients with RA has been realized more and more in China and the Chinese-speaking regions during the last two decades. There still exist certain shortcomings, however, in the validation of disease-specific instruments in particular for use in clinical settings. To facilitate the clinical use of HRQOL in patients with RA and improve the quality of research, there is a strong need of validating the HRQOL instruments in more locations with a larger population, more comprehensive validity, and potential cross-cultural validation in future.

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